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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,307	05/31/2001	Stephen F. Badylak	3220-68450	3375

7590 07/01/2002
Barnes & Thornburg
11 South Meridian Street
Indianapolis, IN 46204

EXAMINER

MATHEW, FENN C

ART UNIT	PAPER NUMBER
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3764

DATE MAILED: 07/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,307

Applicant(s)

BADYLAK ET AL.

Examiner

Fenn Mathew

Art Unit

3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 31 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. In claim 1, the phrase "the a damaged or diseased portion" is vague and indefinite.
4. In claim 3, the phrases, "the tunica submucosa", "the tunica muscularis", "the luminal portion" and "the tunica mucosa" lack antecedent basis.
5. In claim 8, the phrase "a single thickness sheet" is vague an indefinite.
6. In claim 9, the phrase "the a damage or diseased portion" is vague and indefinite.
7. In claim 10, the phrase "the head and neck soft tissues" lacks antecedent basis.
8. Claim 11 provides for the use of vertebrate submucosa or vertebrate basement membrane to manufacture a non-immunogenic tissue graft, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper

definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wexler et al. ((1989, September). Phonosurgical studies: fat-graft reconstruction of injured canine vocal cords. *Annals of otology, rhinology, and laryngology*, p668-673). Wexler et al. disclose a method for repair of damaged vocal cord tissues comprising the steps of removing the damaged portion and replacing the removed portion with a graft construct comprising vertebrate submucosa.

11. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Cobb et al. (International Publication No. WO 98/10775). Cobb et al. disclose a method for the repair of damaged head and neck soft tissues comprising the steps of removing the damaged or diseased portion and replacing the removed portion of tissue with a graft construct comprising vertebrate submucosa. (p. 15-19).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 2-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wexler et al. ((1989, September). Phonosurgical studies: fat-graft reconstruction of injured canine vocal cords. Annals of otology, rhinology, and laryngology, p668-673). in view of Badylak et al. (U.S. Patent No. 5,573,784). Wexler et al. disclose the claimed invention except for where the submucosa is derived from. Badylak et al. disclose the use of intestinal submucosa as a tissue graft. It would have been obvious to one having ordinary skill in the art at the time of invention to provide Wexler et al. with a tissue graft made of intestinal submucosa, as disclosed by Badylak et al. in order to repair diseased or damaged tissues.

14. Referring to claim 3, Wexler et al., as modified by Badylak et al. above disclose submucosa comprised of intestinal submucosa comprising the tunica submucosa delaminated from the tunica muscularis and the luminal portion of the tunica mucosa. (See Badylak et al. abstract)

15. Referring to claim 5, the feature of having the graft construct comprise 2-12 layers of submucosa is a matter of design choice.

16. Referring to claim 6, the feature of having the graft construct comprise 4-6 layers is a matter of design choice.

17. Referring to claim 7, Wexler et al., as modified by Badylak et al. above disclose a graft comprised of a multi-layer homolaminate.

18. Referring to claim 8, Wexler et al. as modified by Badylak et al. above disclose the claimed invention except for the graft being a single sheet. It would have been obvious to one having ordinary skill in the art at the time of invention to have a single layer sheet in order to provide a thinner and more lightweight graft.

19. Referring to claim 10, Wexler et al., as modified by Badylak et al. above in claim 8 disclose repair of vocal cord tissue.

20. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wexler et al. ((1989, September). Phonosurgical studies: fat-graft reconstruction of injured canine vocal cords. Annals of otology, rhinology, and laryngology, p668-673). in view of Badylak (International Publication No. WO 98/25637). Wexler et al. disclose the claimed invention except for the use of vertebrate basement membrane. Badylak discloses the use of vertebrate basement membrane as a substitute for applications using intestinal submucosa (page 1, lines 15-25). It would have been obvious to one having ordinary skill in the art at the time of invention to substitute vertebrate basement membrane as taught by Badylak for the intestinal submucosa disclosed by Wexler et al. as an alternative means of forming grafts.

Conclusion

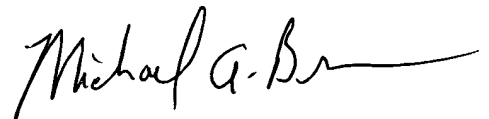
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fenn Mathew whose telephone number is (703) 305-2846. The examiner can normally be reached on Monday - Friday 9:00am - 5:30pm.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

fcm
June 29, 2002



Michael A. Brown
Primary Examiner